Application Serial No.: 10/022,481

Corrected Amendment and Response dated August 2, 2004

Reply to Notice of Non-compliant Amendment dated July 2, 2004

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Amendments to the Specification:

Please substitute the below paragraph for paragraph 36:

--In one embodiment of the invention, shown in Figure 1A, a method using a direct assay format is provided to detect the free form of the first member 1BP of a binding pair BP comprising a first 1BP and second member 2BP. In step 1 of the method, a first particle 1p bound to the second member 2BP is provided in a suitable reaction buffer at a concentration of between about 5×10^{10} and 1×10^{13} particles per ml. The particle solution is contacted with an aliquot of sample (e.g., human plasma or other body fluids or fluid samples), which is preferably about 1/20 the volume of particle solution forming a reacted sample.--

Please substitute the below paragraph for paragraph 39:

--In the second step, as shown in Figure 1B, a second particle solution comprising second particles 2p bound to a third member 3BP at a concentration of about 5 x 10¹¹ and 1 x 10¹⁴ particles per ml is contacted with the reacted sample for a period sufficient to allow agglutination, preferably between about 2-5 minutes. The third member 3BP is capable of binding to the first member 1BP but is different from the second member 2BP; i.e., it binds at a different, single binding site on the first member. The second particle 2p itself may be the same as, or different from, the first particle 1p. The third member 3BP bound to the second particle 2p will bind to any first complex 1c, forming a second complex 2c illustrated in FIG. 1C. The third member 3BP will also bind to any remaining free first member 1BP in solution and to first member 1BP bound to second member 2BP (see complex 3c in Figure 1). However, only formation of the second complex 2c and the formation of a bridge between first and second particle, 1p and 2p, will be detectable as an agglutination reaction, measurable as a change in turbidity of the sample.--